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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,950	12/08/2000	Colin Watts	ERP01.004A	2538

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,950

Applicant(s)

WATTS, COLIN

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-21, 38-42 and 52-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52-54 and 61 is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 11, 13-17, 19, 38-42 and 55-60 is/are rejected.
- 7) ☒ Claim(s) 10, 12, 18 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/GB99/00963.

Claims 5-7, 21-37 and 43-51 have been canceled.

Claims 1-4, 8-20, 38-42, and 52-61 are currently pending and are the subject of examination in the present Office Action.

Claim 55 was previously omitted from the grounds of rejection, and has now been included. Accordingly, this Office Action is made NON-FINAL.

Claim Objections

1. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Base claim 1 recites "competitive."
2. Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

In view of Applicant's amendment filed May 12, 2005 and Applicant's arguments filed January 21, 2005, the following ground of rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 15-17, 19, 38-42, 55, 56 and 60 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting an immune response in a patient comprising administering one of the N- and C-terminal blocked peptides AENK or KNNE as set forth in claim 18 or with a peptide of the structure B1-(X)_n-Asn-Q as set forth in claim 20 and the peptides themselves, does not reasonably provide enablement for the full scope of asparaginyl endopeptidase inhibitors or their administration of in general. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims read upon the use of any inhibitor of asparaginyl endopeptidase in the claimed method. However, the specification discloses only two specific terminally blocked tetramer peptides and peptides that satisfy the chemical formula $B1-(X)_n\text{-Asn-Q}$ as set forth in claim 12, for example. The specification does not disclose the use or suitability of any other type of asparaginyl endopeptidase inhibitor for administration to a patient for inhibition of enzyme activity and subsequent immune responsiveness. Additionally, other than the disclosed peptides that bind and interfere with the asparagine-cysteine cleavage site of the enzyme, the specification does not teach the artisan how to make any other type of inhibitor of the asparaginyl endopeptidase enzyme. The term includes in scope ALL agents or compounds that would inhibit the enzyme, such as potential inorganic or organic small molecules, carbohydrates or immunoglobulins, for example, even inclusive of inhibitors of transcription such as DNA-binding proteins or antisense molecules for example. However, the specification fails to disclose any of these molecules and does not teach the artisan how to make or how to use any of them. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

The claims have not been amended and Applicant has not traversed the ground of rejection as applied to non-amended claims. Accordingly the ground of rejection stands as previously presented for this subset of claims.

2. In view of Applicant's amendment filed May 12, 2005 and Applicant's arguments filed January 21, 2005, the following ground of rejection is maintained as it applies to the amended claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 8, 9, 11, 13-17, 19, 38-42 and 55-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting an immune response

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in a patient comprising administering one of the N- and C-terminal blocked peptides AENK or KNNE as set forth in claim 10 or with a peptide of the structure B1-(X)_n-Asn-Q as set forth in claim 12 and the peptides themselves, does not reasonably provide enablement for the full scope of inhibiting an immune response for the full scope of asparaginyl endopeptidase inhibitors that are "asparagine-containing." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is maintained for the reasons of record.

Applicant's arguments filed January 21, 2005 have been fully considered but they are not persuasive.

Claim 1 has been amended to read upon the use of any inhibitor of asparaginyl endopeptidase that "is a peptide comprising an asparagine-containing peptide." Applicant asserts that the full scope of the claimed invention is enabled because the specification teaches how to make peptide derivatives and "[s]uch peptide derivatives presumably can be made with conventional procedures known to an artisan." The mere fact that the peptide comprises an asparagine-containing peptide says nothing about the structural properties making the peptide a competitive inhibitor. Stating that the artisan would "presumably" know how to make a competitive inhibitor merely puts forth an assumption, not a showing that the artisan would be enabled to practice the full scope of the claimed invention without undue experimentation.

Accordingly, it is maintained that in view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

4. The following new ground of rejection has been necessitated by Applicant's amendment filed May 12, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 11 recites the limitation "wherein the inhibitor is a non-competitive or irreversible inhibitor" in line 1. There is insufficient antecedent basis for this limitation in the claim. The base claim specifically recites a "competitive" inhibitor.

Conclusion

7. Claims 52-54 and 61 are allowed.

8. Claims 10, 12, 18 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *RV*
Patent Examiner
October 13, 2004

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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